AUG 1 0 2001

Tab 4

Premarket Notification [510(k)] Summary

K011024

April 3, 2001

Trade Name: CyberKnife System

Common Name: Linear Accelerator for Radiation Therapy

Classification Name: Medical Linear Accelerator Accessory, 90 IYE (per 21 CFR section 892.5050)

Manufacturer's Name: Accuray Incorporated
Address: 570 Del Rey Avenue
Sunnyvale, CA 94085

Corresponding Official: E. Bruce Floyd
Title: Vice President Quality Assurance & Regulatory Affairs
Telephone: 408-522-3740
Fax: 408-522-3749

Predicate Device: Accuray CyberKnife® System for Stereotactic Radiosurgery/Radiotherapy, K000478

Device Description: The CyberKnife® System is a treatment planning, imaging, and delivery system for image-guided stereotactic radiosurgery and precision radiotherapy. The treatment planning system provides 3-dimensional viewing of the patient anatomy and implanted fiducials with appropriate dose calculation of the target volume and surrounding tissue structures. The imaging system provides real-time, orthogonal x-ray images of the patient to verify treatment position and alignment. The imaging system and software provides for 3-D and 6-D tracking of skull and implanted fiducials along the x, y and z axis and rotations about each axis. It then transmits the information for dynamic positioning and accurate pointing of the linear accelerator. The treatment delivery system consists of a 6 MV x-ray producing linear accelerator. A six-access manipulator provides automated positioning and pointing of the linear accelerator in 3-D translations. The CT data set handling software supports up to 300 CT slices. The CT/MR fusion feature allows viewing of both CT

reference and MR dataset images. The patient support system provides for positioning and alignment of the patient.

Intended Use: To provide treatment planning and image guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

Technological Characteristics: Refer to Tab 9.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2001

Mr. E. Bruce Floyd
Vice President Quality Assurance
and Regulatory Affairs
Accuray Incorporated
570 Del Rey Avenue
SUNNYVALE CA 94085

Re: K011024
Cyberknife System V3.0 (Linear Accelerator)
Dated: July 10, 2001
Received: July 11, 2001
Regulatory Class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Floyd:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Tab 3

Indications For Use

510(k) Number: K011024

Device Name: CyberKnife System

Indications for Use:
To provide treatment planning and image guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011024

Prescription Use √ OR Over-The-Counter Use___
(per 21 CFR 801.109)